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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,720	12/13/2001	Shu Hui Chen	X-11811	6118
25885	7590	04/28/2004	EXAMINER	
ELI LILLY AND COMPANY			LUKTON, DAVID	
PATENT DIVISION				
P.O. BOX 6288			ART UNIT	PAPER NUMBER
INDIANAPOLIS, IN 46206-6288			1653	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

David Lukton

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6 and 8-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

Pursuant to preliminary amendment (filed 12/12/01), claim 7 has been cancelled, and claims 1-3, 6, 8-13 amended. Claims 1-6, 8-13 are pending.

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Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 2, 10, 11, drawn to a compound of formula I.
2. Claims 3-5, drawn to a compound of undefined structure which could be made (but does not have to be made) by the process steps recited in claim 3.
3. Claim 6, drawn to a compound of undefined structure which could be made (but does not have to be made) by the process steps recited in claim 6.
4. Claim 8, drawn to a method of preparing a compound, wherein the structure of the compound is only partially defined.
5. Claim 9, drawn to a method of preparing a compound, wherein the structure of the compound is only partially defined.
6. Claims 12-13, drawn to a method of treating a fungal infection.

The claimed inventions are distinct.

Inventions 1 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that Group 1 is elected, and claims found allowable, the corresponding method-of-use claims will be rejoined therewith.

Inventions {2, 3} and {4, 5} are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). However, in the event that either of Groups 2 or 3 is elected, and claims therein found allowable, the corresponding "method-of-making" claims will be rejoined therewith (subject to the same limitations on the structure of the target compounds).

Groups 2 and 3 differ from group 1 in that, in the Group 2-3 claims, the structure is not defined. It is noted that in claim 3, lines 1-2, the following phrase is used:

"compound prepared by the steps of".

However, it is assumed that by "of" is meant *comprising*. This assumption is made, in part, because process steps are missing. For example, a chemist carrying out the procedures would likely employ standard "work-up" and isolation procedures at one or more points during the process. In the absence of such, a complex mixture is likely.

Once the term "comprising" is in place, any and all subsequent chemical reactions are

included. For example, the chlorine atom could be displaced by an alkyl amine or a thiol; thus, the presence of a chlorine atom is not actually required in the final structure. Or the olefin at residue 7 could be epoxidized, or could be reacted with a thiol which will undergo a 1, 4 addition to the enone. Or any of the primary amines in the molecule can be acylated. There are numerous other possibilities as well. Furthermore, the compound does not actually have to be synthesized by the indicated process steps. For example, step (iii) of claim 3 recites the use of certain benzotriazoles. Perhaps the coupling process works better if these particular ones are used. But there are many other azahydroxy-benzotriazoles which could be used (see, e.g., USP 5,580,981); moreover, the coupling reaction can be made to occur without any benzotriazoles present. Accordingly, the search for the Group 2 and 3 inventions would have to extend to any compound which could have been made beginning with the indicated starting materials, and which could be made by alternative synthesis procedures.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no

generic claim is finally held to be allowable. A "specie" in this case is a specific compound, with all substituent variables fully accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1806